

SEP 3 1996

# Zaxis

A new dimension in Technology

K940785

510(k) SUMMARY  
LFS Lipogel Assay Kit  
February 23, 1996

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), premarket notification was in accordance with 21 CFR 807.87 and the SMDA.

1. Submitter of 510(k)

Company: Zaxis, Inc.  
1890 Georgetown Road  
Hudson, Ohio 44236

Attn: Kenneth W. Egger  
Sales and Marketing Manager

Telephone: (216) 650-0444  
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2. Name of Device:

A. Trade/Proprietary Name:

LFS Lipogel Assay Kit

B. Common/Usual Name:

Electrophoretic Gel and Reagents for Lipoprotein Separation

C. Classification Name:

21 CFR 862.1475 "Lipoprotein Test System"

Note: This classification name is in accordance with FDA's publication "Classification Names for Medical Devices and In Vitro Diagnostic Products" (FDA 91-4246). "Lipoproteins Electrophoretic Separation" is cited as the standard product nomenclature in this publication with 21 CFR 862.1475 "Lipoprotein Test System" cited as the corresponding regulation.

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3. **Sponsor/Manufacturer:**

Company: Zaxis, Inc.  
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Hudson, Ohio 44236

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4. **Reason for Submitting the 510(k)**

This 510(k) is being submitted for the LFS Lipogel Assay Kit which is a new device. The LFS Lipogel Assay Kit is substantially equivalent to legally marketed predicate devices.

5. **Device Description**

The LFS Lipogel Assay Kit utilizes a gel electrophoresis method for separating lipoproteins. The principle of electrophoresis is based upon the fact that lipoproteins, when placed in an electrical field, will migrate toward one of the electrode poles. The lipids in human plasma are bound to protein and circulate throughout the body as complexes known as lipoproteins. Routine electrophoresis separates lipoprotein complexes into four generally distinct, well-resolved fractions or zones. Each fraction is composed of one or more individual lipoproteins. From the fastest migrating to the slowest, these fractions have been designated as alpha lipoproteins (high density lipoproteins - HDL), pre-beta lipoproteins (very low density lipoproteins - VLDL), beta lipoproteins (low density lipoproteins - LDL), and chylomicrons.

The resulting pattern may be visually interpreted or quantified. After electrophoresis, the lipoproteins in the gel are immobilized in a fixative solution. The lipoprotein pattern is visualized by staining the gel with a lipid-specific stain. With the use of a densitometer, the relative percentage of each lipoprotein fraction can be determined.

The LFS Lipogel Assay Kit is a complete system containing the reagents, gels, and hardware necessary to perform electrophoretic separation of lipoproteins.

6. Intended Use

The LFS Lipogel Assay Kit is indicated for the electrophoretic separation of lipoproteins in a gradient polyacrylamide gel. That is, the LFS Lipogel Assay Kit is an *in vitro* diagnostic device intended to test human plasma or serum for lipoproteins and their subfractions.

7. Substantial Equivalence

The LFS Lipogel Assay Kit has substantially equivalent intended uses and technological characteristics to those of legally marketed predicate devices. The LFS Lipogel Assay Kit, like the predicate devices, is an *in vitro* diagnostic device intended to test human plasma or serum for lipoproteins and their subfractions. Further, the LFS Lipogel Assay Kit, as well as the predicate devices, are merely laboratory gel electrophoresis systems specifically designed for the separation of lipoproteins. Provided in Table 1 is a comparison of the LFS Lipogel Assay Kit characteristics to that of legally marketed predicate devices.

Table 3-1  
Comparison of Technological Characteristics  
LFS Lipogel Assay Kit and Predicate Devices

Manufacturer	Zaxis, Inc.	Helena Laboratories	Beckman Instruments
Device	LFS Lipogel Assay Kit	Titan Gel-Lipoprotein Electrophoresis System	Paragon™ Electrophoresis System Lipoprotein Reagent Test Kit
510k Number	Current 510(k)	K833611	K854057
Principle of Operation	Electrophoresis	Electrophoresis	Electrophoresis
Components	Electronics and Reagents	Electronics and Reagents	Electronics and Reagents
Gel	Polyacrylamide	Agarose	Agarose
Stain	Sudan Black	Sudan Red	Sudan Black
Fractions	VLDL, LDL, HDL	VLDL, LDL, HDL	VLDL, LDL, HDL

Performance testing was conducted on the LFS Lipogel Assay Kit to characterize its performance and demonstrate its substantial equivalence to legally marketed predicate devices. The LFS Lipogel Assay Kit was tested for within-run and between-runs reproducibility. The reproducibility of the LFS Lipogel Assay Kit between laboratories was, also, examined. Lastly, the performance of the LFS Lipogel Assay Kit was compared against that of a legally marketed predicate device, the Helena Laboratories' Titan Gel-Lipoprotein Electrophoresis System (K833611). The data demonstrate the substantial equivalence of the LFS Lipogel Assay Kit to legally marketed predicate devices.

In conclusion, the LFS Lipogel Assay Kit, is substantially equivalent to legally marketed predicates.